

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
  - TEXT CUT OFF AT TOP, BOTTOM OR SIDES
  - FADED TEXT
  - ILLEGIBLE TEXT
  - SKEWED/SLANTED IMAGES
  - COLORED PHOTOS
  - BLACK OR VERY BLACK AND WHITE DARK PHOTOS
  - GRAY SCALE DOCUMENTS
- 

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**



PATENT  
Customer No. 22,852  
Attorney Docket No. 08157.0015

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Paul GILSON et al.

Application No.: 09/986,132

Filed: November 7, 2001

For: SUPPORT FRAME FOR AN  
EMBOLIC PROTECTION  
DEVICE

)  
)  
)  
) Group Art Unit: 3762  
)  
) Examiner: Unknown  
)  
)  
)

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

**CLAIM FOR PRIORITY**


Under the provisions of Section 119 of 35 U.S.C., Applicants hereby claim the benefit of the filing date of International Patent Application No. PCT/IE99/00035, filed May 7, 1999 for the above-identified United States Patent Application.

In support of Applicants' claim for priority, a certified copy of the priority application is filed herewith.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: January 28, 2002

By:   
Roland G. McAndrews, Jr.  
Reg. No. 41,450

271673\_1

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
www.finnegan.com



Patents Office  
Government Buildings  
Hebron Road  
Kilkenny

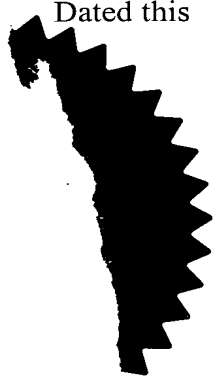
I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No. PCT/IE99/00035

Date of Filing 7 May 1999

Applicant SALVIAC LIMITED, an Irish company of 39-40 Upper Mount Street, Dublin 2, Ireland.

Dated this 17 day of August 2001.



19 An officer authorised by the  
Controller of Patents, Designs and Trademarks.

PCT

## REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

HOME COPY

Receiving Office use only

PCT/IE 99/00035

International Application No.

= 7. MAY 1999

International Filing Date 10.05.99

IRISH PATENTS OFFICE

Name of receiving Office and PCT International Application

Applicant's or agent's file reference  
(if desired) (12 characters maximum)

SALV10/C/WO

## Box No. I TITLE OF INVENTION

"Support Frame for Embolic Protection Device"

## Box No. II APPLICANT

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

SALVIAC LIMITED  
39-40 Upper Mount Street  
Dublin 2  
Ireland

☐ This person is also inventor.

Telephone No.

Facsimile No.

Teleprinter No.

State (that is, country) of nationality:

IE

State (that is, country) of residence:

IE

This person is applicant  
for the purposes of:☐ all designated  
States☒ all designated States except  
the United States of America☒ the United States  
of America only☐ the States indicated in  
the Supplemental Box

## Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

GILSON, Paul  
Uggool  
Moycullen  
County Galway  
Ireland

This person is:

☐ applicant only☒ applicant and inventor☐ inventor only (If this check-box  
is marked, do not fill in below.)

State (that is, country) of nationality:

IE

State (that is, country) of residence:

IE

This person is applicant  
for the purposes of:☐ all designated  
States☐ all designated States except  
the United States of America☒ the United States  
of America only☐ the States indicated in  
the Supplemental Box☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

## Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf  
of the applicant(s) before the competent International Authorities as:

☒ agent☐ common representative

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

O'BRIEN, John A; WELDON, Michael J,  
c/o John A O'Brien & Associates,  
Third Floor, Duncairn House,  
14 Carysfort Avenue,  
Blackrock,  
County Dublin,  
Ireland

Telephone No.

+ 353 1 2883877

Facsimile No.

+ 353 1 2993878

Teleprinter No.

☐ Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

*If none of the following sub-boxes is used, this sheet should not be included in the request.*

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

GILVARRY, Michael  
Rathroe  
Kilcon  
Ballina  
County Mayo  
Ireland

This person is:

- ☐ applicant only  
☒ applicant and inventor  
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

IE

State (that is, country) of residence:

IE

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

- ☐ applicant only  
☐ applicant and inventor  
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

- ☐ applicant only  
☐ applicant and inventor  
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

- ☐ applicant only  
☐ applicant and inventor  
☐ inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant for the purposes of:

- ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.

## Box No. V DESIGNATION STATES

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes, at least one must be marked):

## Regional Patent

- ☒ AP ARIPO Patent: GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SZ Swaziland, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ EA Eurasian Patent: AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ EP European Patent: AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ OA OAPI Patent: BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line) .....

## National Patent (if other kind of protection or treatment desired, specify on dotted line):

- |  |  |
|--|--|
| <input checked="" type="checkbox"/> AL Albania .....                               | <input checked="" type="checkbox"/> LS Lesotho .....                                   |
| <input checked="" type="checkbox"/> AM Armenia .....                               | <input checked="" type="checkbox"/> LT Lithuania .....                                 |
| <input checked="" type="checkbox"/> AT Austria .....                               | <input checked="" type="checkbox"/> LU Luxembourg .....                                |
| <input checked="" type="checkbox"/> AU Australia .....                             | <input checked="" type="checkbox"/> LV Latvia .....                                    |
| <input checked="" type="checkbox"/> AZ Azerbaijan .....                            | <input checked="" type="checkbox"/> MD Republic of Moldova .....                       |
| <input checked="" type="checkbox"/> BA Bosnia and Herzegovina .....                | <input checked="" type="checkbox"/> MG Madagascar .....                                |
| <input checked="" type="checkbox"/> BB Barbados .....                              | <input checked="" type="checkbox"/> MK The former Yugoslav Republic of Macedonia ..... |
| <input checked="" type="checkbox"/> BG Bulgaria .....                              | <input checked="" type="checkbox"/> MN Mongolia .....                                  |
| <input checked="" type="checkbox"/> BR Brazil .....                                | <input checked="" type="checkbox"/> MW Malawi .....                                    |
| <input checked="" type="checkbox"/> BY Belarus .....                               | <input checked="" type="checkbox"/> MX Mexico .....                                    |
| <input checked="" type="checkbox"/> CA Canada .....                                | <input checked="" type="checkbox"/> NO Norway .....                                    |
| <input checked="" type="checkbox"/> CH and LI Switzerland and Liechtenstein .....  | <input checked="" type="checkbox"/> NZ New Zealand .....                               |
| <input checked="" type="checkbox"/> CN China .....                                 | <input checked="" type="checkbox"/> PL Poland .....                                    |
| <input checked="" type="checkbox"/> CU Cuba .....                                  | <input checked="" type="checkbox"/> PT Portugal .....                                  |
| <input checked="" type="checkbox"/> CZ Czech Republic .....                        | <input checked="" type="checkbox"/> RO Romania .....                                   |
| <input checked="" type="checkbox"/> DE Germany ..and utility model .....           | <input checked="" type="checkbox"/> RU Russian Federation .....                        |
| <input checked="" type="checkbox"/> DK Denmark ..and utility model .....           | <input checked="" type="checkbox"/> SD Sudan .....                                     |
| <input checked="" type="checkbox"/> EE Estonia .....                               | <input checked="" type="checkbox"/> SE Sweden .....                                    |
| <input checked="" type="checkbox"/> ES Spain .....                                 | <input checked="" type="checkbox"/> SG Singapore .....                                 |
| <input checked="" type="checkbox"/> FI Finland .....                               | <input checked="" type="checkbox"/> SI Slovenia .....                                  |
| <input checked="" type="checkbox"/> GB United Kingdom .....                        | <input checked="" type="checkbox"/> SK Slovakia .....                                  |
| <input checked="" type="checkbox"/> GD Grenada .....                               | <input checked="" type="checkbox"/> SL Sierra Leone .....                              |
| <input checked="" type="checkbox"/> GE Georgia .....                               | <input checked="" type="checkbox"/> TJ Tajikistan .....                                |
| <input checked="" type="checkbox"/> GH Ghana .....                                 | <input checked="" type="checkbox"/> TM Turkmenistan .....                              |
| <input checked="" type="checkbox"/> GM Gambia .....                                | <input checked="" type="checkbox"/> TR Turkey .....                                    |
| <input checked="" type="checkbox"/> HR Croatia .....                               | <input checked="" type="checkbox"/> TT Trinidad and Tobago .....                       |
| <input checked="" type="checkbox"/> HU Hungary .....                               | <input checked="" type="checkbox"/> UA Ukraine .....                                   |
| <input checked="" type="checkbox"/> ID Indonesia .....                             | <input checked="" type="checkbox"/> UG Uganda .....                                    |
| <input checked="" type="checkbox"/> IL Israel .....                                | <input checked="" type="checkbox"/> US United States of America .....                  |
| <input checked="" type="checkbox"/> IN India .....                                 | <input checked="" type="checkbox"/> UZ Uzbekistan .....                                |
| <input checked="" type="checkbox"/> IS Iceland .....                               | <input checked="" type="checkbox"/> VN Viet Nam .....                                  |
| <input checked="" type="checkbox"/> JP Japan .....                                 | <input checked="" type="checkbox"/> YU Yugoslavia .....                                |
| <input checked="" type="checkbox"/> KE Kenya .....                                 | <input checked="" type="checkbox"/> ZW Zimbabwe .....                                  |
| <input checked="" type="checkbox"/> KG Kyrgyzstan .....                            |  |
| <input checked="" type="checkbox"/> KP Democratic People's Republic of Korea ..... |  |
| <input checked="" type="checkbox"/> KR Republic of Korea .....                     |  |
| <input checked="" type="checkbox"/> KZ Kazakhstan .....                            |  |
| <input checked="" type="checkbox"/> LC Saint Lucia .....                           | <input checked="" type="checkbox"/> ZA South Africa .....                              |
| <input checked="" type="checkbox"/> LK Sri Lanka .....                             | <input checked="" type="checkbox"/> AE United Arab Emirates .....                      |
| <input checked="" type="checkbox"/> LR Liberia .....                               | <input type="checkbox"/> .....   |

Check-boxes reserved for designating States (for the purposes of a national patent) which have become party to the PCT after issuance of this sheet:

**Precautionary Designation Statement:** In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)

Box No. VI PRIORITY CLAIM		<input type="checkbox"/> Further priority claims are indicated in the Supplemental Box.		
Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is:		
		national application: country	regional application: regional Office	international application: receiving Office
item (1)				
item (2)				
item (3)				

☐ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office) identified above as item(s):

\* Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(iii)). See Supplemental Box.

## Box No. VII INTERNATIONAL SEARCHING AUTHORITY

**Choice of International Searching Authority (ISA)**  
(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):

ISA /EP

**Request to use results of earlier search; reference to that search** (if an earlier search has been carried out by or requested from the International Searching Authority):

Date (day/month/year)

Number

Country (or regional Office)

## Box No. VIII CHECK LIST; LANGUAGE OF FILING

This international application contains the following number of sheets:

request : 4

description (excluding sequence listing part) : 10

claims : 2

abstract : 1

drawings : 9

sequence listing part of description :

Total number of sheets : 26

This international application is accompanied by the item(s) marked below:

1. ☒ fee calculation sheet2. ☐ separate signed power of attorney3. ☒ copy of general power of attorney; reference number, if any: 39802, 398454. ☐ statement explaining lack of signature5. ☐ priority document(s) identified in Box No. VI as item(s):6. ☐ translation of international application into (language):7. ☐ separate indications concerning deposited microorganism or other biological material8. ☐ nucleotide and/or amino acid sequence listing in computer readable form9. ☐ other (specify):

Figure of the drawings which should accompany the abstract:

Fig. 15

Language of filing of the international application:

English

## Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).



John O'Brien

For receiving Office use only		2. Drawings:	
1. Date of actual receipt of the purported international application: 7. MAY 1999 107.05.99)		<input checked="" type="checkbox"/> received:	
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:		<input type="checkbox"/> not received:	
4. Date of timely receipt of the required corrections under PCT Article 11(2):			
5. International Searching Authority (if two or more are competent): ISA /EP	6. <input type="checkbox"/> Transmittal of search copy delayed until search fee is paid		

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

- 1 -

**"SUPPORT FRAME FOR EMBOLIC PROTECTION DEVICE"**

This invention relates to a filter element for a transcatheter embolic protection device.

5

Introduction

The invention is particularly concerned with filter elements for transcatheter embolic protection devices of the type described in our previously filed PCT Patent Application No. PCT/IE98/00093 the contents of which are incorporated herein by reference. One type of such embolic filter essentially comprises a filter body mounted on an associated collapsible support frame which can be collapsed against the guide wire by means of a catheter for deployment of the filter through a patient's vascular system. Upon retraction of the catheter the support frame and filter body expand outwardly from the guidewire across a blood vessel within which the filter is positioned to filter blood flowing through the blood vessel.

10  
15

The support structure is generally of shaped memory material such as nitinol which provides the circumferential pressure on expansion to secure the filter bodies in a close fit within the vessel. When the filter element is being pulled through a small diameter conduit or opening, there are certain forces exerted on the support frame. The first is on entry of the proximal end into the tube and when the whole of the proximal end has been inserted into the tube and the distal end is about to be inserted into the catheter tube. Considerable loading forces are generated which in some cases require considerable retraction forces to overcome.

20  
25

The present invention is directed towards overcoming this problem.

30



- 2 -

Statements of Invention

According to the invention there is provided an embolic protection device comprising:

5

a collapsible filter element for delivery through a vascular system of a patient;

10

the filter being movable between a collapsed stored position for movement through the vascular system, and an expanded position for occluding a blood vessel such that blood passing through the blood vessel is delivered through the filter element;

15

the filter element comprising a collapsible filter body and a filter support frame;

20

the collapsible filter body having an inlet end and an outlet end, the inlet end of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body, the outlet end of the filter body having a plurality of outlet openings sized to allow through passage of blood but to retain undesired embolic material within the filter body;

25

the filter support frame being movable between a collapsed position for movement through the vascular system and an extended outwardly projecting position to support the filter body in the expanded position;

characterised in that

30

the filter support frame comprises a plurality of support elements, some of the support elements providing support for a first portion of the filter body

- 3 -

and others of the support elements providing support for a second portion of the filter body.

5 In a preferred embodiment of the invention the first portion is a proximal portion of the filter body which is supported by proximal support elements.

In one embodiment of the invention the second portion is a distal portion of the filter body which is supported by distal support elements.

10 The proximal support elements preferably comprise a plurality of proximal support arms. Preferably there are three substantially equi-spaced proximal support arms.

15 Preferably the distal support elements comprise a plurality of distal support arms. Preferably there are three substantially equi-spaced distal support arms.

#### Brief Description of the Drawings

20 The invention will be more clearly understood by the following description of some of the embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which: -

Fig. 1 is partially sectioned elevational view an embolic protection device;

25 Fig. 2 is a schematic sectional elevational view of the embolic protection device of Fig. 1;

Fig. 3 is a detail sectional view of portion of the device of Fig. 1;

30 Fig. 4 is a longitudinal cross sectional view of the device of Fig. 1;

- 4 -

Fig. 5 is a cross sectional view of a distal end of the device of Fig. 1;

Fig. 6 is a view on the line A-A in Fig. 5;

5 Fig. 7 is a perspective view of a filter body of the device of Figs. 1 to 6;

Fig. 8 is a side elevational view of the filter body of Fig. 7;

Fig. 9 is a view on a proximal end of the filter body;

10

Fig. 10 is a perspective view of a support frame of the device of Figs. 1 to 6;

Fig. 11 is a side elevational view of the support frame;

15

Fig. 12 is a perspective view illustrating the manufacture of the support frame;

Fig. 13 is a view of the support frame and filter element assembly;

20

Fig. 14 is a longitudinal cross sectional view of a filter element according to the invention;

Fig. 15 is a longitudinal cross sectional view a support frame of the filter element of Fig. 14;

25

Fig. 16 is a cross sectional on the line III-III of Fig. 15;

Fig. 17 is a cross sectional view on the line IV-IV of Fig. 15;

30

Fig. 18 is a cross sectional view on the line V-V of Fig. 15; and

Fig. 19 is a longitudinal cross section view of another support frame.

Detailed Description

5 Referring to Figs. 1 to 13 there is illustrated an embolic protection device as described in our co-pending Application PCT/IE98/00093 indicated generally by the reference number 100. The device 100 has a guidewire 101 with a proximal end 102 and a distal end 103. A tubular sleeve 104 is slidably mounted on the guidewire 101. A collapsible filter 105 is mounted on the sleeve 104, the filter 105  
10 being movable between a collapsed stored position against the sleeve 104 and an expanded position as shown in the drawings extended outwardly of the sleeve 104 for deployment in a blood vessel.

The sleeve 104 is slidable on the guidewire 101 between a pair of spaced-apart end  
15 stops, namely an inner stop 106 and an outer stop which in this case is formed by a spring tip 107 at the distal end 103 of the guidewire 101.

The filter 105 comprises a filter body 110 mounted over a collapsible support frame 111. The filter body 110 is mounted to the sleeve 104 at each end, the body 110 being rigidly attached to a proximal end 112 of the sleeve 104 and the body  
20 110 being attached to a collar 115 which is slidable along a distal end 114 of the sleeve 104. Thus the distal end of the body 110 is longitudinally slidable along the sleeve 104. The support frame 111 is also fixed at the proximal end 112 of the sleeve 104. A distal end 116 of the support frame 111 is not attached to the sleeve  
25 104 and is thus also free to move longitudinally along the sleeve 104 to facilitate collapsing the support frame 111 against the sleeve 104. The support frame 111 is such that it is naturally expanded as shown in the drawings and can be collapsed inwardly against the sleeve 104 for loading in a catheter 118 or the like.

30 The filter body 105 has large proximal inlet openings 117 and small distal outlet openings 119. The proximal inlet openings 117 allow blood and embolic material

- 6 -

to enter the filter body, however, the distal outlet openings 119 allow through passage of blood but retain undesired embolic material within the filter body.

5 An olive guide 120 is mounted at a distal end of the sleeve 104 and has a cylindrical central portion 121 with tapered ends 122, 123. The distal end 122 may be an arrowhead configuration for smooth transition between the catheter and olive surfaces. The support frame 111 is shaped to provide a circumferential groove 125 in the filter body 110. If the filter is too large for a vessel, the body may crease and this groove 125 ensures any crease does not propagate along the  
10 filter.

Enlarged openings are provided at a proximal end of the filter body 110 to allow ingress of blood and embolic material into an interior of the body 110.

15 In use, the filter 105 is mounted in a collapsed state within a distal end of the catheter 118 and delivered to a deployment site. When the filter is correctly positioned the catheter 118 is retracted allowing the support frame 111 to expand expanding the filter body 110 across the vessel in which the filter is mounted. Blood and emboli can enter the enlarged openings at a proximal end of the filter  
20 body 110. The blood will pass through the net wall, however, the openings or pores in the net are sized so as to retain the embolic material. After use the catheter is delivered along the guidewire 101 and slid over the filter 105 engaging the proximal inlet end 112 first to close the openings and then gradually collapsing the filter body against the sleeve 104 as the catheter 118 advances over the filter  
25 105. Once the filter 105 is fully loaded in the catheter 118, it can then be withdrawn.

It will be noted that a proximal end of the filter is fixed and a distal end of the filter is longitudinally movable along the sleeve to facilitate collapsing of the filter  
30 body.

- 7 -

Further, the catheter engages the proximal end of the filter body first thus closing the filter body inlet and preventing escape of embolic material from the filter body as the filter body is being collapsed.

5 The outer filter body 110 is preferably of a resilient biocompatible elastomeric material. The material may be a polyurethane based material. There are a series of commercially available polyurethane materials that may be suitable. These are typically based on polyether or polycarbonate or silicone macroglycols together with diisocyanate and a diol or diamine or alkanolamine or water chain extender.  
10 Examples of these are described in EP-A-461,375 and US 5,621, 065. In addition, polyurethane elastomers manufactured from polycarbonate polyols as described in US 5,254,622 (Szycher) are also suitable.

The filter material may also be a biostable polycarbonate urethane article an  
15 example of which may be prepared by reaction of an isocyanate, a chain extender and a polycarbonate copolymer polyol of alkyl carbonates. This material is described in our co-pending PCT Application No. IE98/00091, filed November 9, 1998, the entire contents of which are incorporated herein by reference. The filter material may be manufactured from a block and cut into a desired shape.  
20 However the filter is preferably formed by dipping a rod of desired geometry into a solution of the material which coats the rod. The rod is then dissolved. The final geometry of the filter may be determined in the dipping step or the final geometry may be achieved in a finishing operation. Typically the finishing operations involve processes such as mechanical machining operations, laser  
25 machining or chemical machining.

The filter body is of hollow construction and is formed as described above by dipping a rod in a solution of polymeric material to coat the rod. The rod is then dissolved, leaving a hollow body polymeric material. The rod may be of an  
30 acrylic material which is dissolved by a suitable solvent such as acetone.

- 8 -

The polymeric body thus formed is machined to the shape illustrated in Figs. 1 to 13. The final machined filter body comprises an inlet or proximal portion 210 with a proximal neck 212, and outlet or distal portion 213 with a distal neck 214, and an intermediate portion 215 between the proximal and distal portions.

5

The inlet holes 117 are provided in the proximal portion 210 which allow the blood and embolic material to flow into the filter body. In this case the proximal portion 210 is of generally conical shape to maximise the hole size.

10

The intermediate portion 215 is also hollow and in this case is of generally cylindrical construction. This is important in ensuring more than simple point contact with the surrounding blood vessel. The cylindrical structure allows the filter body to come into soft contact with the blood vessel to avoid damaging the vessel wall.

15

The intermediate portion 215 is provided with a radial stiffening means, in this case in the form of a radial strengthening ring or rim 220. The ring 220 provides localised stiffening of the filter body without stiffening the material in contact with the vessel. Such an arrangement provides appropriate structural strength so that line apposition of the filter body to the vessel wall is achieved. It is expected that other geometrics of stiffening means will achieve a similar result.

20

25

The tubular intermediate portion 215 is also important in maintaining the stability of the filter body in situ to retain captured emboli and to ensure that flow around the filter is minimised. For optimum stability we have found that the ratio of the axial length of the intermediate portion 215 of the filter body to the diameter of the intermediate portion 215 is preferably at least 0.5 and ideally greater than 1.0.

30

The collapsible support frame 111 has four foldable arms 290 which are collapsed for deployment and upon release extend outwardly to expand the filter body 110.

- 9 -

The support frame 111 can be manufactured from a range of metallic or polymeric components such as a shape memory alloy like nitinol or a shape memory polymer or a shaped stainless steel or metal with similar properties that will recover from the deformation sufficiently to cause the filter body 110 to open.

5

The support frame may be formed as illustrated in Fig. 12 by machining slots in a tube 291 of shape memory alloy such as nitinol. On machining, the unslotted distal end of the tube forms a distal collar 293 and the unslotted proximal end of the tube forms a proximal collar 294. In use, the distal collar 293 is slidably moveable along the tubular sleeve 104 which in turn is slidably mounted on the guidewire 101 for deployment and retrieval. The proximal collar 294 is fixed relative to the tubular sleeve 104.

10

To load the filter the sub assembly of the support frame and filter body is pulled back into the catheter 118 to engage the distal stop 107. The support arms 290 are hinged inwardly and the distal collar 293 moves forward along the tubular sleeve 104. As the support arms 290 enter the catheter 118 the filter body 110 stretches as the filter body collar 115 slides along the tubular sleeve 104 proximal to the olive 120. On deployment, the catheter 118 is retracted proximally along the guidewire 101 initially bringing the collapsed filter assembly with it until it engages the proximal stop 106. The catheter sleeve then begins to pull off the filter freeing the support arms 290 to expand and the filter body apposes the vessel wall.

20

For retrieval, a retrieval catheter is introduced by sliding it over the guidewire 101 until it is positioned at the proximal end of the filter body and support frame. Pulling the guidewire 101 will initially engage the distal stop 107 with the filter element and begin to pull it into the retrieval catheter. The initial travel into the delivery catheter acts to close the proximal openings of the filter element, thus entrapping the embolic load. As the filter continues to be pulled back the filter

25

30



- 10 -

body and the support frame are enveloped in the retrieval catheter. The collapsed filter may then be removed from the patient.

5 Referring to Figs. 14 to 18 there is illustrated a support frame indicated generally by the reference numeral 30 for a filter 31.

10 The filter support frame comprises a plurality of support elements some of which provide support for one portion of the filter body 31 and some of which provide support for another portion of the filter body 31. In this case there are six support arms, three arms 20, 21, 22 providing support for a proximal end of the filter body 31 and three arms 23, 24, 25 providing support for a distal end of the filter body 31.

15 In this way the loading forces are greatly reduced, while at the same time the integrity of the filter is maintained. Thus, the filter can be more easily loaded and retrieved.

20 Referring to Fig. 19 there is illustrated another support frame 40 similar to that of Figs. 14 to 18. In this case adequate support is provided while omitting the distal collar 293. This frame 40 is more easily formed and the same principle may be applied to other frames as those described above.

25 The invention is not limited to the embodiments hereinbefore described which may be varied in both construction and detail.

Claims

## 1. An embolic protection device comprising:

5 a collapsible filter element for delivery through a vascular system of a patient;

the filter being movable between a collapsed stored position for movement through the vascular system, and an expanded position for occluding a blood vessel such that blood passing through the blood vessel is delivered through the filter element;

the filter element comprising a collapsible filter body and a filter support frame;

15 the collapsible filter body having an inlet end and an outlet end, the inlet end of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body, the outlet end of the filter body having a plurality of outlet openings sized to allow through passage of blood but to retain undesired embolic material within the filter body;

the filter support frame being movable between a collapsed position for movement through the vascular system and an extended outwardly projecting position to support the filter body in the expanded position;

characterised in that

30 the filter support frame comprises a plurality of support elements, some of the support elements providing support for a first portion of

- 12 -

the filter body and others of the support elements providing support for a second portion of the filter body.

- 5        2.    An embolic protection device as claimed in claim 1 wherein the first portion is a proximal portion of the filter body which is supported by proximal support elements.
- 10       3.    An embolic protection device as claimed in claim 1 or 2 wherein the second portion is a distal portion of the filter body which is supported by distal support elements.
- 15       4.    An embolic protection device as claimed in claim 2 or 3 wherein the proximal support elements comprise a plurality of proximal support arms.
- 20       5.    An embolic protection device as claimed in claim 4 wherein there are three substantially equi-spaced proximal support arms.
6.    An embolic protection device as claimed in any of claims 3 to 5 wherein the distal support elements comprise a plurality of distal support arms.
- 25       7.    An embolic protection device as claimed in claim 6 wherein there are three substantially equi-spaced distal support arms.
8.    An embolic protection device substantially as hereinbefore described with reference to the accompanying drawings.

- 13 -

Abstract

5 A support frame 30 for an embolic protection filter 31. Three arms 20, 21, 22 provide support for a proximal end of the filter body 31 and three arms 23, 24, 25 provide support for a distal end of the filter body 31. In this many loading and deployment forces are reduced.

1/9

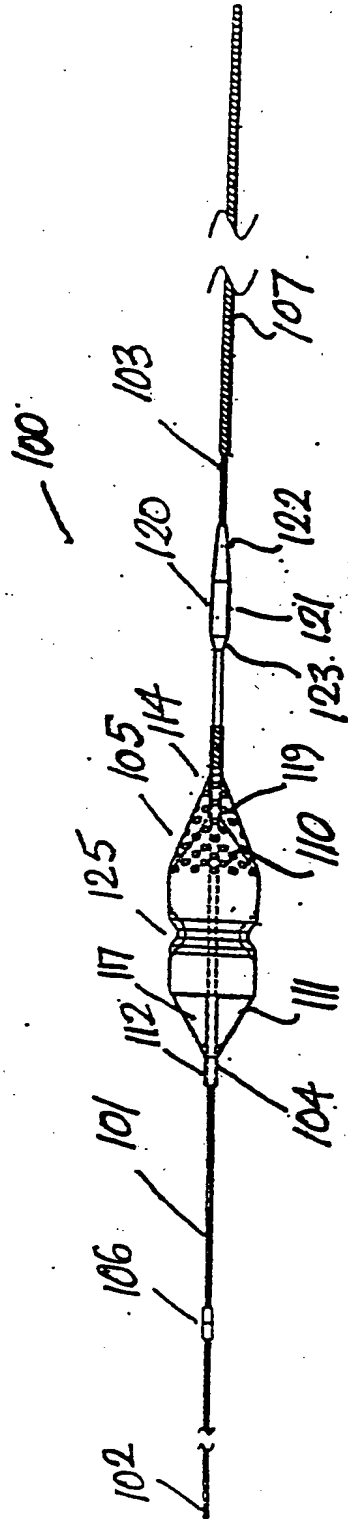
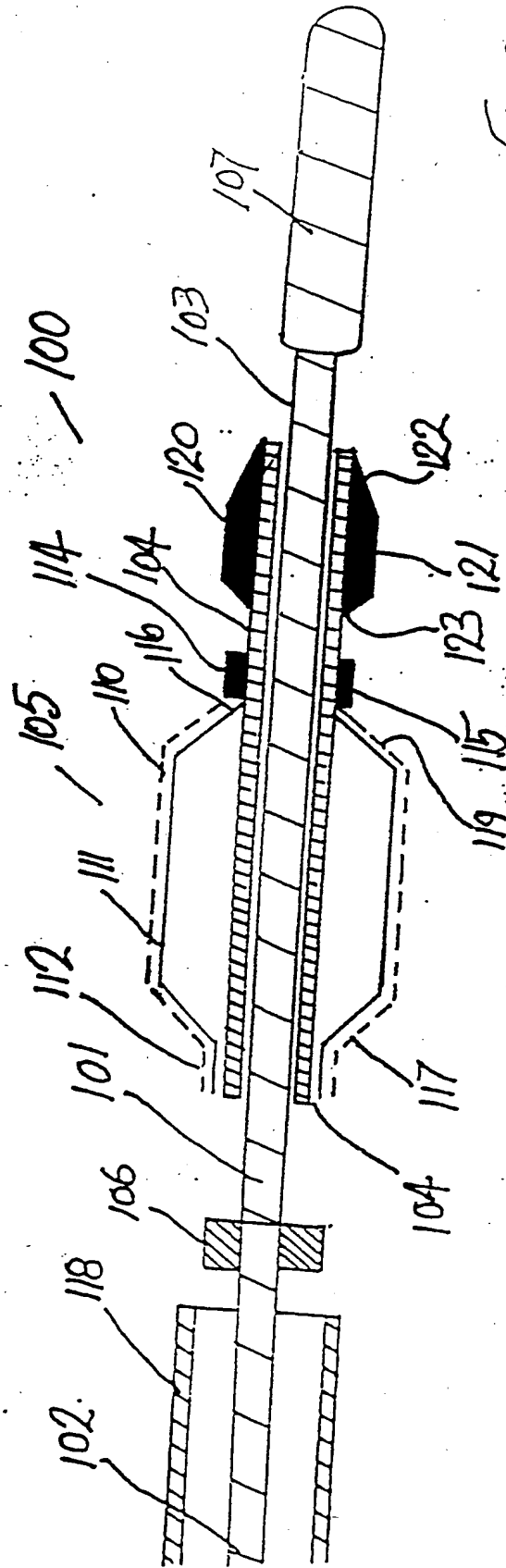
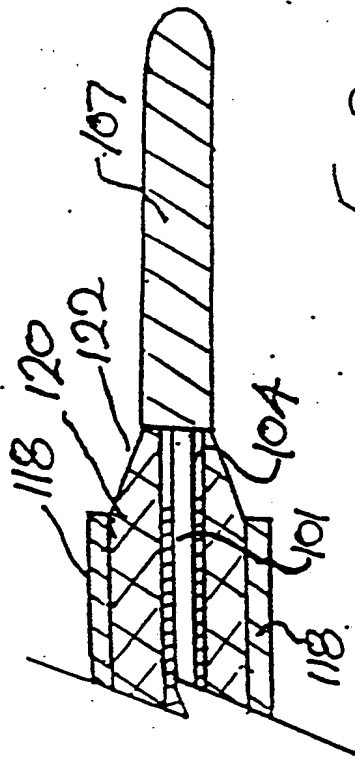


Fig. 1

2/9



3/9

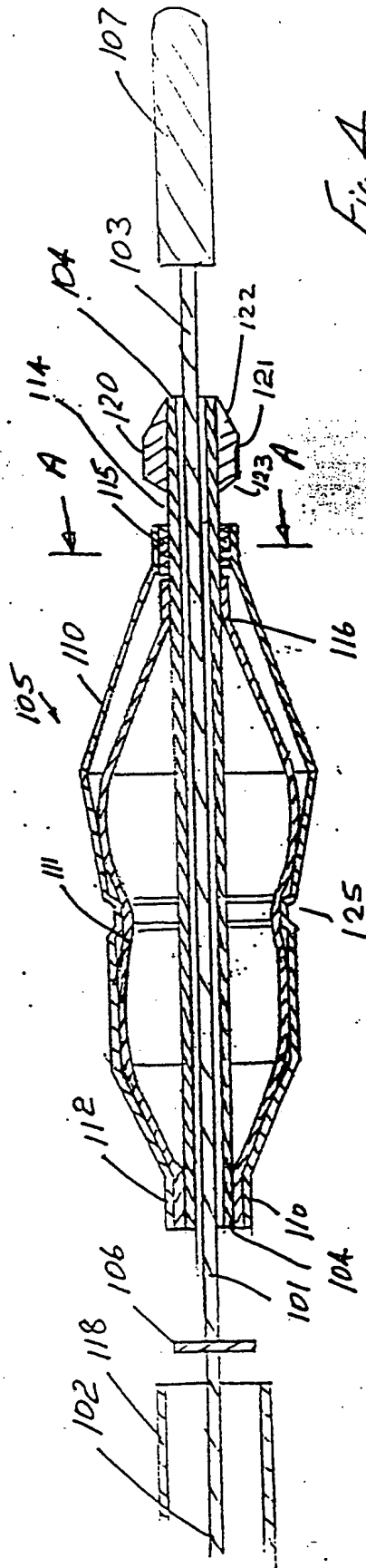


Fig. 4

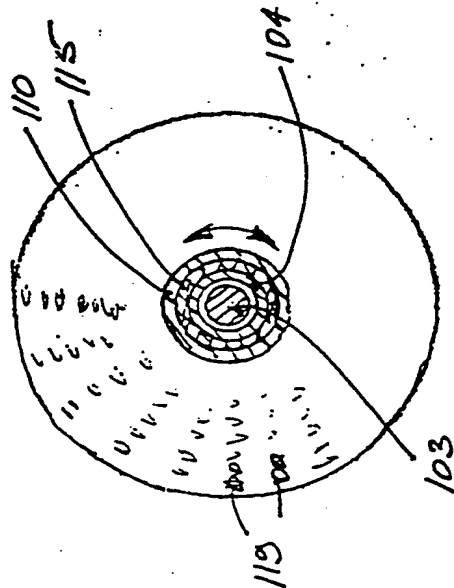


Fig. 6

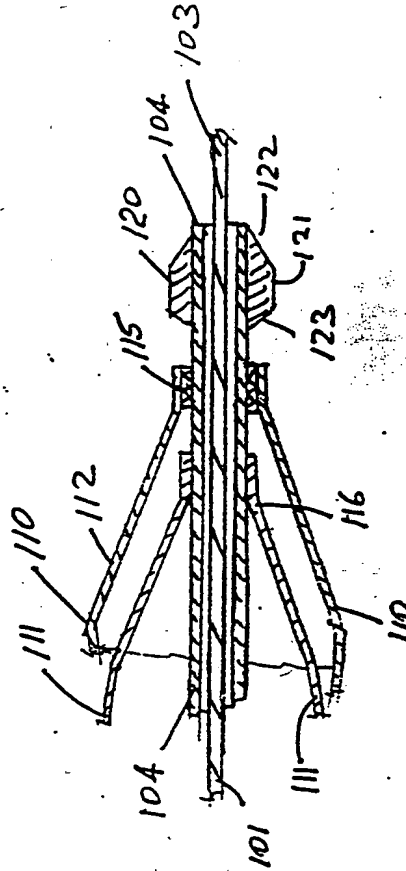


Fig. 5

4/9

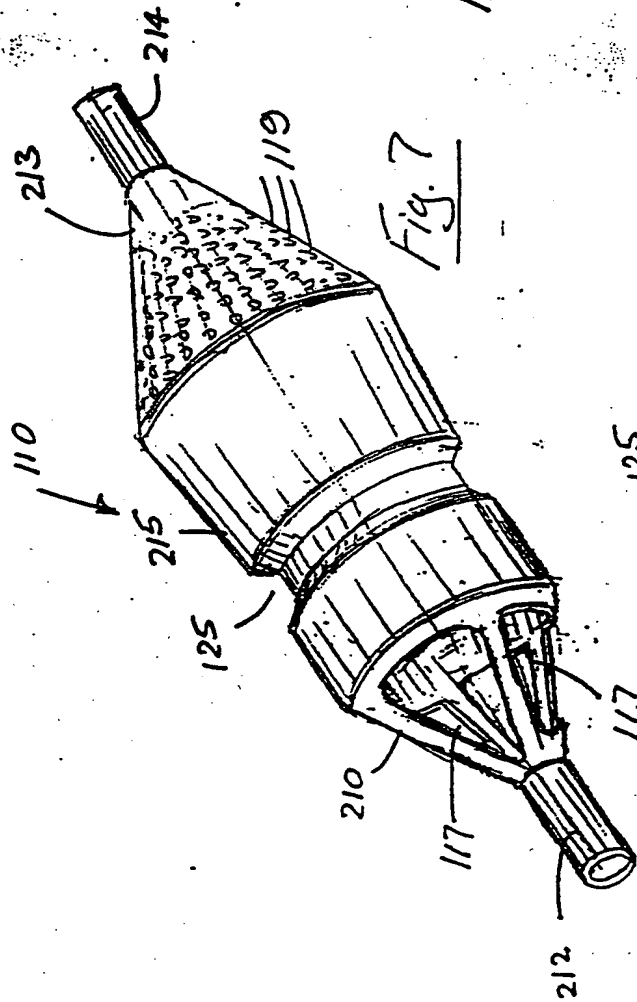


Fig. 7

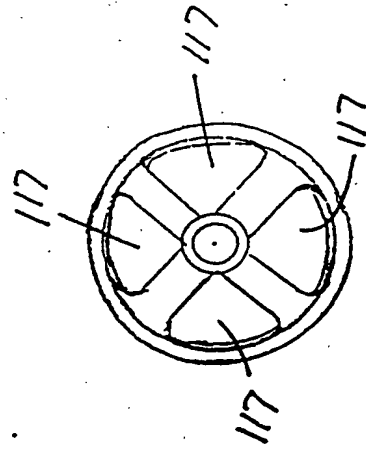


Fig. 9

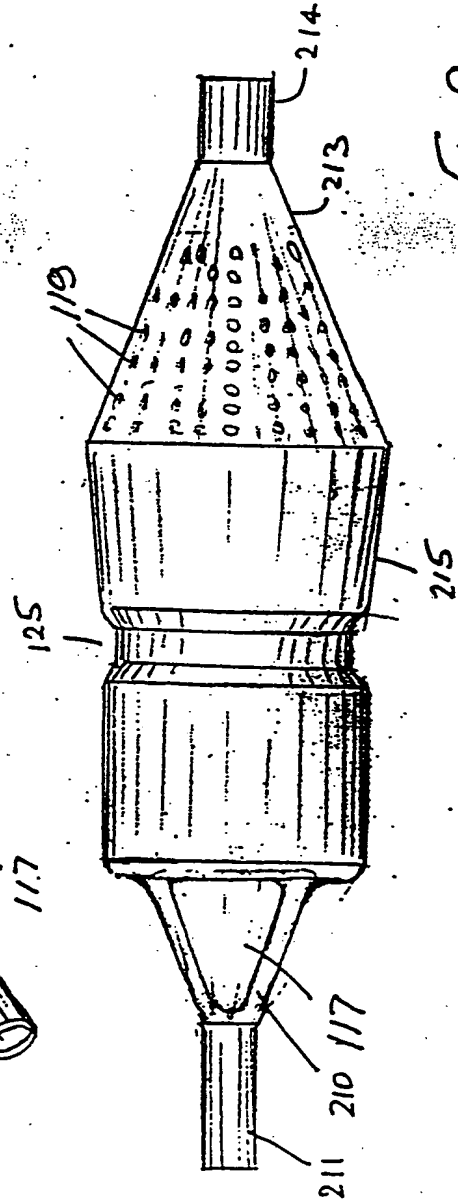
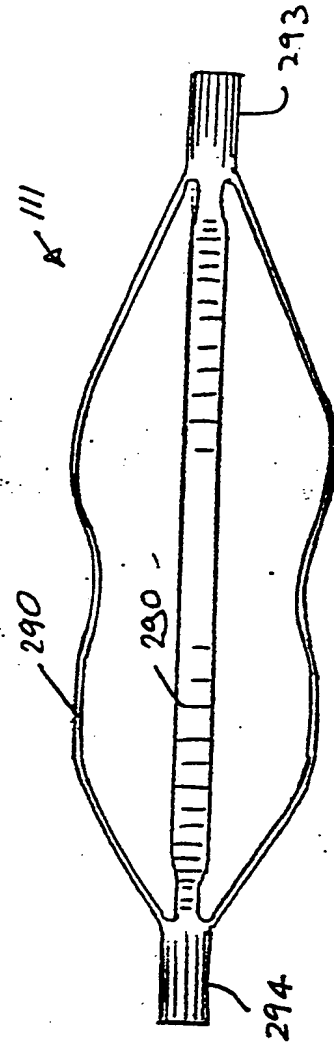
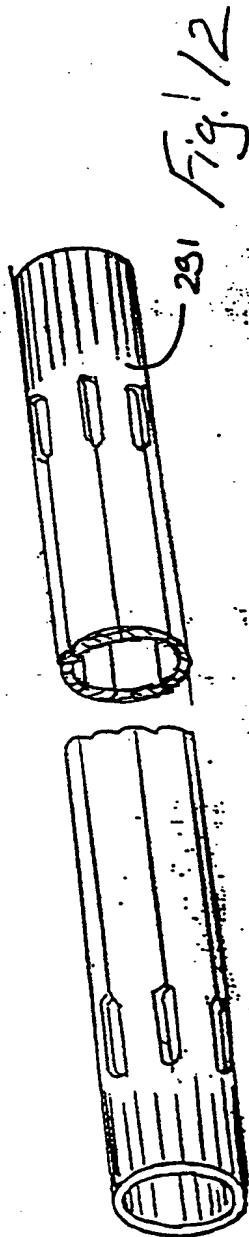
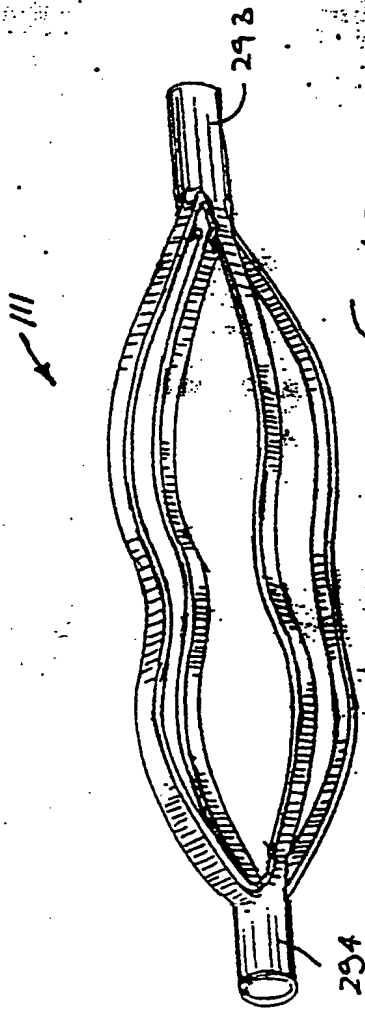


Fig. 8

A



5/9



6/9

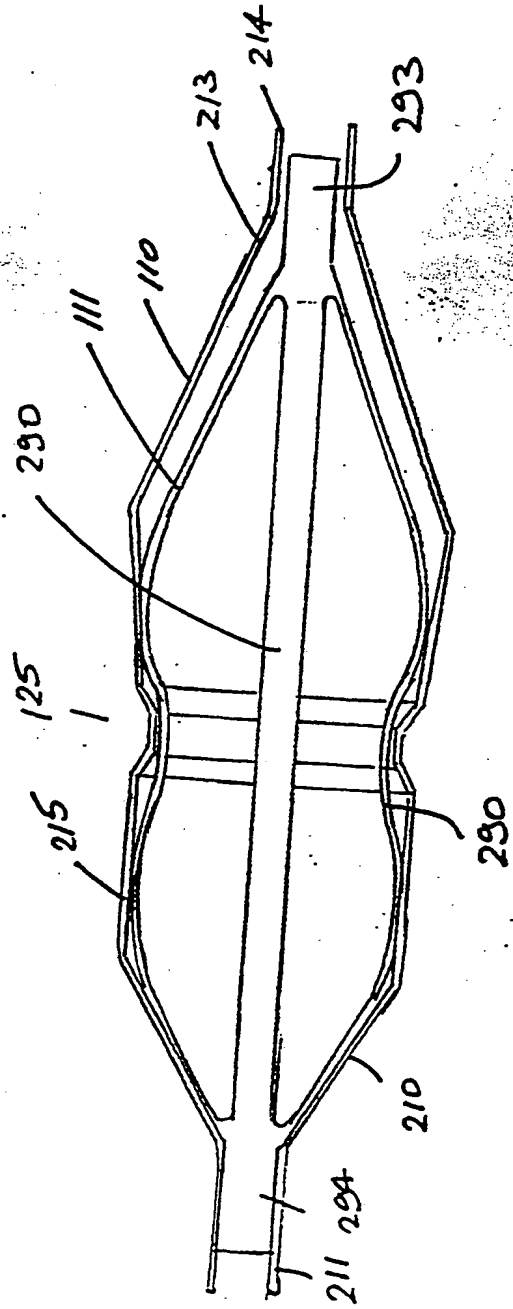


Fig. 13

7/9

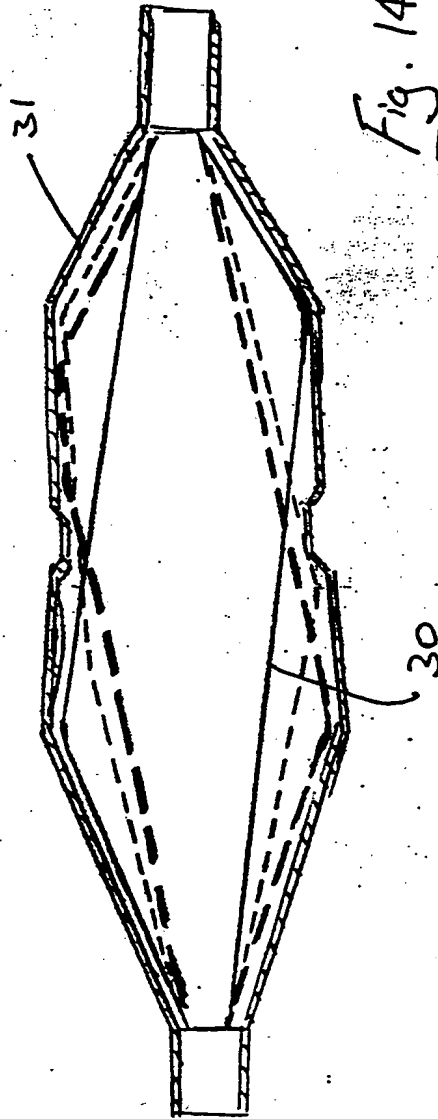
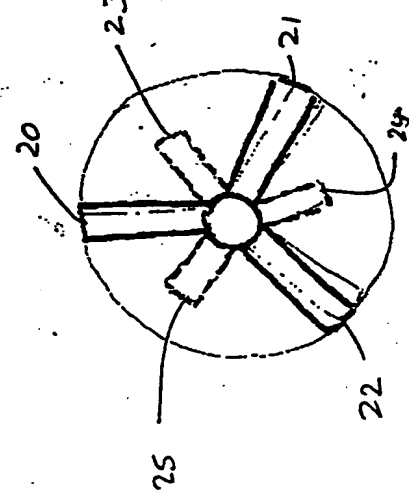
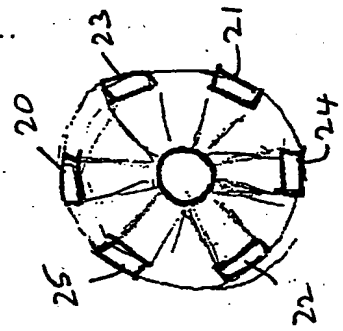
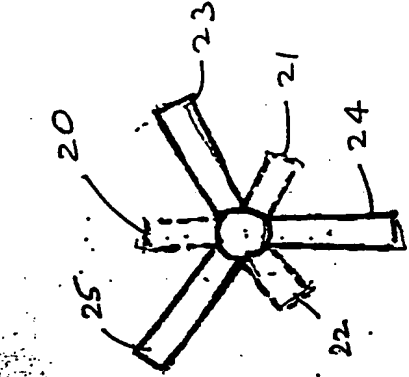
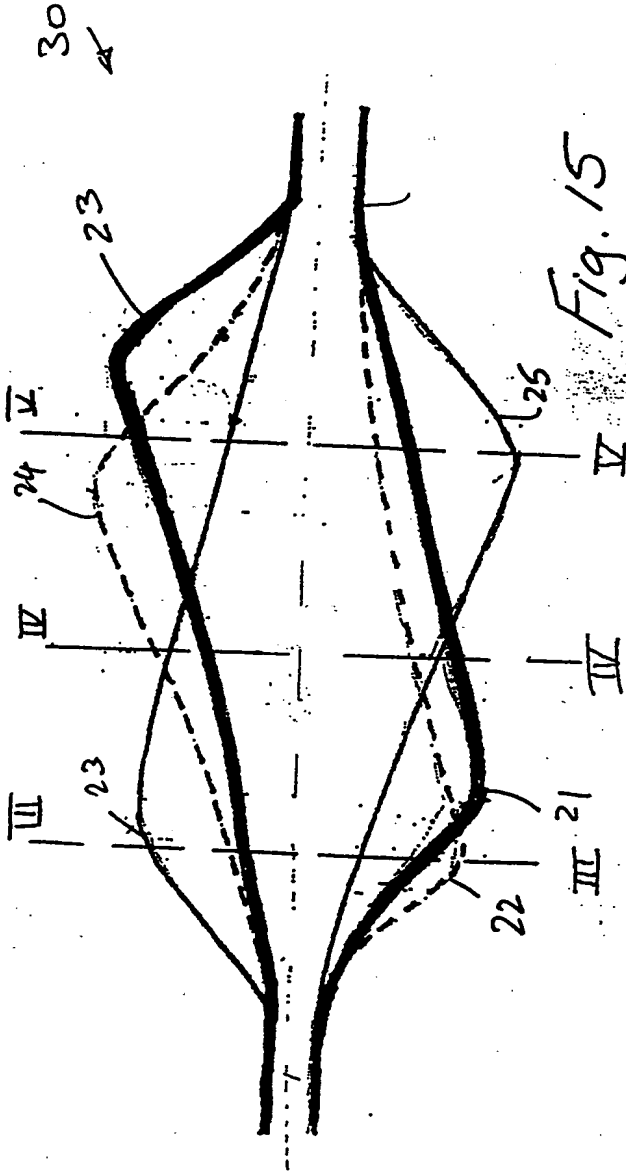


Fig. 14

8/9



9/9

40

4

Fig. 19

